# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA

| CARDIAC PACEMAKERS, INC. and GUIDANT SALES CORPORATION                          | )<br>)                               |
|---|--------------------------------------|
| Plaintiffs,   | ) ) Civil Action No. 04-1016 JMR/FLN |
| v.  | )                                    |
| ST. JUDE MEDICAL, INC.,<br>ST. JUDE MEDICAL S.C., INC. and<br>PACESETTER, INC., | ) ) (JURY TRIAL DEMANDED)            |
| Defendants.   | )<br>)                               |

## **SECOND AMENDED COMPLAINT**

Plaintiffs Cardiac Pacemakers, Inc. and Guidant Sales Corporation (collectively, "Guidant") bring this action for patent infringement against Defendants St. Jude Medical, Inc., St. Jude Medical S.C., Inc. and Pacesetter, Inc. (collectively "SJM"). Guidant alleges as follows:

#### **PARTIES**

- 1. Plaintiff Cardiac Pacemakers, Inc. ("CPI") is a Minnesota corporation having its principal place of business in St. Paul, Minnesota. CPI develops and manufactures cardiac rhythm management ("CRM") devices, including implantable pacemakers, defibrillators, and cardiac resynchronization devices, and associated products such as leads.
- 2. Plaintiff Guidant Sales Corporation ("GSC") is an Indiana corporation having its principal place of business in Indianapolis, Indiana. GSC is a wholly-owned subsidiary of CPI. GSC sells in the United States CRM devices and leads manufactured by CPI.

- 3. Upon information and belief, Defendant St. Jude Medical, Inc. ("St. Jude") is a Minnesota corporation having its principal place of business at One Lillehei Plaza, St. Paul, Minnesota 55117. St. Jude through its CRM division also manufactures and sells CRM devices as well as associated leads.
- 4. Upon information and belief, Defendant St. Jude Medical S.C., Inc. ("SJSC") is a Minnesota corporation having its principal place of business at One Lillehei Plaza, St. Paul, Minnesota 55117. SJSC sells cardiac stimulation devices, specifically those manufactured by Pacesetter, Inc.
- 5. Upon information and belief, Defendant Pacesetter, Inc. ("Pacesetter") is a Delaware corporation having its principal place of business in Sylmar, California. Pacesetter is wholly-owned by St. Jude, is part of its CRM division and is a competitor of Guidant in the development, manufacture, and sale of CRM devices and leads.

# **JURISDICTION AND VENUE**

- 6. This action arises under the Acts of Congress relating to patents, Title 35, United States Code.
- 7. This Court has subject matter jurisdiction over the claims in this Complaint under 28 U.S.C. §§ 1331 and 1338(a).
  - 8. Venue in this judicial district is proper under 28 U.S.C. §§ 1391(c) and 1400(b).

### **PATENTS-IN-SUIT**

9. On May 26, 1998, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 5,755,766, entitled "Open-Ended Intravenous Cardiac Lead" naming as

the inventors, Stuart R. Chastain, Bruce A. Tockman, and Randy W. Westlund. A copy of U.S. Patent No. 5,755,766 is attached hereto as Exhibit A.

- 10. On December 14, 2001, CPI filed reexamination application No. 90/006,157 in the U.S. Patent and Trademark Office requesting reexamination of U.S. Patent No. 5,755,766. On February 24, 2004, the U.S. Patent and Trademark Office duly and legally issued Reexamination Certificate No. 5,755,766 C1 attached hereto as Exhibit B (hereinafter the original patent and the reexamination certificate are collectively referred to as "the '766 patent"). The entire right, title, and interest in the '766 patent is owned by CPI, which exclusively licenses its wholly-owned subsidiary, GSC, to sell leads which fall within the scope of the '766 patent claims.
- 11. On May 31, 2005, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 6,901,288, entitled "Sealing Assembly for Intravenous Lead" naming as the inventors Aaron W. Janke, Larry L. Hum, Randy Westlund, Ronald W. Heil, Jr., and Bruce Tockman. A copy of U.S. Patent No. 6,901,288 (hereinafter referred to as "the '288 patent") is attached hereto as Exhibit C. The entire right, title, and interest in the '288 patent is owned by CPI, which exclusively licenses its wholly-owned subsidiary, GSC, to sell leads which fall within the scope of the '288 patent claims.

## THE QUICKSITE MODEL K

12. On information and belief, SJM manufactures a lead known as the QuickSite™ 1056K pacing lead ("QuickSite Model K"). The QuickSite Model K is a unipolar lead placed in the coronary veins to enable left ventricular pacing in cardiac resynchronization applications. A copy of a marketing piece for the QuickSite Model K is attached hereto as Exhibit D.

- 13. On December 19, 2003, SJM submitted to the FDA the final data and results from its clinical investigation of the safety and efficacy of the QuickSite Model K. On information and belief, SJM submitted the QuickSite Model K for FDA approval in the form, or substantially similar form, in which it was being manufactured for commercial sale in Europe and for sale in the United States. On or about June 30, 2004 the FDA approved the QuickSite Model K for sale in the United States.
- 14. On information and belief, SJM began commercial sale in the United States of the QuickSite Model K following receipt of FDA approval.
- 15. On information and belief, SJM manufactures the QuickSite Model K in the United States and is selling the QuickSite Model K commercially in Europe and the United States.

# THE QUICKSITE MODEL T

- 16. On information and belief, SJM manufactures a lead known as the QuickSite<sup>TM</sup> 1056T pacing lead ("QuickSite Model T"). The QuickSite Model T is a bipolar lead placed in the coronary veins to enable left ventricular pacing in cardiac resynchronization applications.
- 17. On information and belief, SJM submitted the QuickSite Model K for FDA approval in the form, or substantially similar form, in which it was being manufactured for commercial sale in Europe and for sale in the United States. On or about April 18, 2005 the FDA approved the QuickSite Model T for sale in the United States.
- 18. On information and belief, SJM began commercial sale in the United States of the QuickSite Model T following receipt of FDA approval.

19. On information and belief, SJM manufactures the QuickSite Model T in the United States and is selling the QuickSite Model T commercially in Europe and the United States.

# **COUNT 1: CLAIM FOR INFRINGEMENT OF THE '766 PATENT**

- 20. SJM has infringed and continues to infringe the '766 patent by making and selling the QuickSite Models K and T in the United States.
- 21. On information and belief, SJM has been aware of U.S. Patent No. 5,755,766 since at least June 1999.
- 22. On information and belief, SJM has knowledge of Guidant's policy of enforcing its intellectual property rights. Nonetheless, on information and belief, SJM has not altered the course of its actions and continues to engage in manufacturing and sales activity in the United States directed toward commercial sale of the QuickSite Models K and T in Europe and the United States.
- 23. Upon information and belief, SJM will continue to infringe the '766 patent unless enjoined by this Court.
  - 24. On information and belief, SJM's infringement of the '766 patent is willful.
- 25. Guidant has no adequate remedy at law for SJM's infringement of the '766 patent. SJM's infringing activities are causing Guidant to suffer irreparable harm and are inflicting damages in an amount not yet determined.

## **COUNT 2: CLAIM FOR INFRINGEMENT OF THE '288 PATENT**

26. SJM has infringed and continues to infringe the '288 patent by making and selling the QuickSite Models K and T in the United States.

- 27. Upon information and belief, SJM will continue to infringe the '288 patent unless enjoined by this Court.
- 28. Guidant has no adequate remedy at law for SJM's infringement of the '288 patent. SJM's infringing activities are causing Guidant to suffer irreparable harm and are inflicting damages in an amount not yet determined.

## **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor and against Defendants, as follows:

- 29. That U.S. Patents Nos. 5,755,766 and 6,901,288 have been infringed by the Defendants and will continue to be infringed by Defendants in the absence of injunctive relief;
- 30. That Defendants and their officers, agents, servants, employees, and all persons in active concert with them, be enjoined from infringing the '766 patent and the '288 patent by making, using, selling or offering to sell the QuickSite Models K and T in the United States;
- 31. Awarding Plaintiffs such other and further relief as this Court deems just and proper;
- 32. Awarding Plaintiffs their lost profits and/or a reasonable royalty in an amount to be proved at trial pursuant to 35 U.S.C. § 284, trebled in the event that willfulness is established;
- 33. Awarding Plaintiffs their costs, disbursements and attorneys' fees in this action pursuant to 35 U.S.C. § 285.
  - 34. Such other relief as the Court deems just and proper.

## **JURY DEMAND**

Plaintiffs demand a jury trial on all claims and all issues so triable.

Dated: August 8, 2005 s/Felicia J. Boyd

Kenneth A. Liebman (#236731) Felicia J. Boyd (#186168) David J.F. Gross (#208772) Julie Knox Chosy (#225228)

## **FAEGRE & BENSON LLP**

90 South Seventh Street 2200 Wells Fargo Center Minneapolis, MN 55402 Tel. No. (612) 766-7000 Fax. No. (612) 766-1600

COUNSEL FOR PLAINTIFFS CARDIAC PACEMAKERS, INC. and GUIDANT SALES CORPORATION

M2:20716257.03